HIV POSITIVE FOSTER CHILDREN IN MEDICAL RESEARCH:

ETHICS OF DISCLOSURE AND ASSENT

Diana Dimitra Popov

Submitted to the faculty of the University Graduate School
in partial fulfillment of the requirements
for the degree
Master of Arts
in the Department of Philosophy,
Indiana University

July 2008

Accepted by the Faculty of Indiana University, in partial fulfillment of the requirements for the degree of Master of Arts.

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Richard Gunderman, MD, PhD, Chair

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John Tilley, PhD

Master's Thesis
Committee

_____

Elaine Cox, MD

ACKNOWLEDGEMENTS

I would like to thank Richard Gunderman MD, PhD, John Tilley PhD, and Elaine Cox MD for agreeing to be on my thesis committee. I would also like to thank Peg Brand PhD, Brooke McMillen, Gale Mercer and my son, William Sizemore.

I would like to also thank the many doctors, including Elaine Cox MD, who work with HIV positive children and their families.

ABSTRACT

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In the early nineties, large numbers of HIV positive children entered the foster care system. At this time, there was no medical treatment available for use in children. A large number of these HIV+ foster children were placed in medical research trials in an attempt to find a safe effective treatment. Medical research conducted on HIV+ children has transformed a once life-threatening illness into a chronic manageable disease. Because children are not always capable of assenting to this research it is important that an independent advocate consents for them. The children should, at a minimum, understand the nature of their illness and that what they are participating in is medical research. Therefore, in order for medical research to occur with foster children who are suffering from a life-threatening illness, the children must know their health status and be allowed to participate in the assent process.

Richard Gunderman MD, PhD

TABLE OF CONTENTS

Chapter One

Often times, being sick is nothing more than a drive to our local drug store where we can find a cure to almost anything that may ail us. If this doesn't help, a doctor can most likely tell us what is wrong, write us a prescription, and send us back to the pharmacy for medicine that promises to make us feel normal within days. No one stops to think about the process it takes to develop and produce these "miracle" medicines.

No one stops to ponder the fact that a drug is made available only because it has been through a process of research protocol and clinical trials. No one stops to question who this person or class of persons was, who bore the burdens, by agreeing to participate in these trials. Were these subjects faced with a medical dilemma because no cure or treatment existed for the illness they suffered and a clinical trial was their last option, or were they simply being altruistic by putting the interests of others above their own? Does anyone ever wonder if that person in the clinical trial volunteered or consented, or was even aware that they were involved in a clinical trial rather than a treatment regimen? Very few people bother to wonder, as they leave the pharmacy with their prescription, about the person who participated in the clinical trial, one of the many phases that allowed the prescription to be approved and made available.

Individuals in this country live in states of distraction that often do not allow the time to ponder these deeper questions about medical care. Every day things like hospitals or pharmacies, schools and books, television, Internet, the highways we drive on, the convenience of travel and reliance on state agencies to protect our public interest, are

things that we not only take for granted, but what we view as the standard (or what some would call the basic minimum) we expect in our society. It is not so much that we take these developments and niceties for granted, but that they have become common to us.

Few people will encounter the evils of a rare or new disease either personally or so close to home that it is impossible to turn away from the implications. Often times it takes a personal experience to force a person not only to care but actually examine and analyze what goes on in our own country, with our own illnesses and available medical treatments. The story and the level of involvement changes greatly when you or a loved one is diagnosed with a life-threatening illness and the doctor cannot write out a prescription to treat you because there is no treatment available, no medicine that has been proven safe and effective. Then, it may actually sink in: the importance of what the medical community, the researchers, the doctors, the ethicists, the trial participants, the different phases of a clinical trial really means.

Even more devastating than dealing with news about our own health or the deterioration of it are cases in which persons are confronted with a sick child. Sometimes parents are faced with the difficult news that this young person has been born with a life-threatening illness, or has contracted one early in life. The child, who is often viewed as too young to understand, is left dependent on medical doctors and parents to make decisions in his best interest.[1]

What happens when there is nothing the doctor can to do to treat a child's illness? Who is responsible for informing the child about his illness or deciding when this

[1] Oberman et al 2003.

information should be given? What happens when the parent(s) abandons the child, or when the child's illness is acquired through the birth process and the mother, who shares the illness, cannot make medical decisions for her child? Should a child ever have a voice in making these decisions about his illness and treatment? What path will be taken when there is no treatment available in the context of medical care and who gets to make these decisions for this child?

The prevalence of intravenous drug users who were having children perpetuated one of the greatest HIV pandemics in the United States, especially New York City, where a majority of these HIV+ children resided.[2] Not only was HIV a new disease that doctors were still learning about, in 1993, doctors knew little about what medicine combinations would work in children.[3] Most of the cases the doctors had dealt with had been with homosexual men and then with intravenous drug users. The medicine that had been developed had not been used or tested in children. No one in the medical arena could have predicted that this disease that at one time exclusively affected the gay community would become prevalent among intravenous drug users who would then infect the bodies and lives of their children. HIV is spread through direct contact which includes blood transfusions, needle sharing with infected persons, sexual contact, transplacental infection, infection during birth, and breast feeding.

> HIV (human immunodeficiency virus) is a virus. HIV is the only virus that can cause AIDS. This type of virus is a retrovirus… There are various stages of HIV, with AIDS generally being the most advanced stage. Many individuals can be infected and contagious with HIV for a period of time and not know that they are HIV positive. This is possible because they do not show any symptoms of the disease, and may not

[2] McNutt 1994.
[3] McNutt 1994.

> realize they have been exposed. HIV makes people sick by attacking the body's immune system. The immune system is the part of the body that defends against infection and disease. The CD4 cell (or T4 cell) is also known as a helper cell. It helps the body fight infections that can lead to illness. This is also the main cell destroyed by HIV. Once the virus enters the body, it targets the CD4 cell, multiplies, and then destroys the CD4 cell. As the amount of virus in the body increases, more and more CD4 cells are destroyed and can no longer fight off illnesses. The individual then begins to have symptoms and gets sick. The amount of time it takes from being infected to developing symptoms varies from person to person. Some patient's will develop symptoms within months of infection and some will take years. The immune system in infants and very young children is still immature, and therefore these children tend to develop symptoms more quickly than newly infected adults.[4]

Doctors, who were accustomed to saving lives, were faced with a moral dilemma. They wanted to help these children, but at this time, no treatment had been approved for use in children. The number of HIV+ children orphaned or abandoned to the state was growing at alarming rates and someone was going to have to make a decision about what to do. "As of June 30, 1993, the Centers for Disease Control and Prevention (CDC) reported 4,710 known AIDS cases in children twelve years-old and younger. At that point, New York City reported 1,124 pediatric AIDS cases which represented twenty-four percent of all cases in the United States."[5]

The majority of these children were no longer under the care of biological parents and were now living in state sponsored foster homes. These homes were not only responsible for caring for these children, but also for ensuring that these children received proper medical care. At this time, no medical treatment was available for HIV+ children.

A decision was made. Foster children who tested positive for HIV were enrolled in Phase I and II clinical trials in an attempt to test HIV drug treatments in children. The

[4] Cox et al.
[5] McNutt 1994.

trials tested AIDS-related medication approved for use in adults in an attempt to slow down the growth of the retrovirus in these HIV+ children. Before a judgment can be made as to whether this was the ethical thing to do, we must first understand what a clinical trial is; we must also understand that no form of treatment besides trials existed for children at this time, and research with infected children was the only way to ensure safe, effective, available treatment for this population.

A drug that is found beneficial in adults cannot necessarily be used in children safely. In order to determine what drug or what amount of a drug is safe in children, participation of children in Phase I and Phase II trials is essential. These trials are crucial to combating and treating childhood illness.

Phase I trials are "Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients."[6] This phase is the least safe for any of the participants. Phase I studies are set up to determine various aspects of the drug(s) in the trial including toxicity, side effects, and effectiveness.[7] Phase II trials are "controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks."[8]

The understanding is that if a benefit occurs to a child during an early phase of a clinical trial, it will be unintended and unforeseen and should never be the reason behind

[6] Clinicaltrials.gov
[7] Clinicaltrials.gov
[8] Clinicaltrials.gov

enrollment. Research trials should not to be confused with medical care, although both contain risks and benefits. These new drugs are not beneficial from the first day they are developed. It is a process, sometimes of trial and error, that will take these new drugs from toxicity to efficacy. This process does not occur on paper, or in a vacuum, but with living individuals who are willing to be the first to expose their bodies to a drug while researchers observe and modify the drug.

The Belmont Report was put in place to ensure that research participants are treated with respect and protected during medical research. According to the Belmont Report, beneficence, respect for persons, and justice[9] is owed to every person who enrolls in a research study. The principle *respect for persons* is at the center of conducting any ethical research with children because children are not fully autonomous agents therefore are "entitled to protection."[10] Respect for persons is an ethical duty that researchers have to each participant in a research trial. This principle usually is interpreted as the competing ethical values of autonomy and paternalism.

Autonomy can be interpreted as every person's unconditional worth or as a "person's right to hold views, to make choices, and to take actions based on personal values and beliefs."[11] In situations where an individual lacks autonomy due to diminished mental capacity or lack of understanding, others may be justified to make decisions on this person's behalf. "Paternalism, then, is *the intentional overriding of one person's known preferences or actions by another person, where the person who overrides justifies the action by the goal of benefiting or avoiding harm to the person*

[9] NBAC, Belmont Report 1979.
[10] NBAC, Belmont Report 1979.
[11] Beauchamp et al 2001.

whose preferences or actions are overridden."[12] The distinction between autonomy and paternalism is relevant to children in medical research because children are individuals with unconditional worth yet are still in need of protection.

Federal guidelines specifically list children and foster children as a class of persons who deserve a greater degree of protection when enrolled in medical research.

> According to 45 CFR 46.409(a):
> Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:
>
> (1) Related to their status as wards; or
> (2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
>
> (b) If the research is approved under paragraph (a) of this section, The IRB shall require appointment of an advocate for each child who is ward, in addition to any other individual acting on behalf of the child as guardian or in *loco parentis*. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

It becomes unethical to enroll foster children, who have been diagnosed with a terminal illness, in medical research unless these children are given the respect owed to them by first disclosing the illness, allowing them the opportunity to discuss the illness, and allowing them a role in deciding whether they should participate in research when no medical treatment is available. Although there is no legal requirement for the assent of foster children diagnosed with a life-threatening illness when no treatment exists, the ethical nature of these trials surrounds the process of disclosure and assent. Disclosure to

[12] Beauchamp et al 2001.

a child of his illness should be the first step before treatment options are discussed. In cases where the child is able to comprehend the nature of his illness he should then be allowed to play a role in the decisions regarding his treatment options especially when no treatment exists outside of medical research.

Assent is an ongoing process of information. The ability to comprehend the information about the research, accompanied with the foster child's ability to understand the nature of his illness, that no medical treatment is available, and that participating in a clinical trial is voluntary, are the minimal aspects that should be discussed and understood. There are no statutory laws on the matter, and what is offered federally, is not legally binding. "At a minimum, most agree that an assent discussion should contain at least an overview of the basic study procedures, a disclosure that participation is voluntary, and an explanation that what the child is being asked to agree to is research rather than medical care per se."[13]

If information is not given to the child, he will make assumptions independently about his illness or the research that may not be correct. The few adults who do have care-giver roles in the lives of these foster children are often strangers introduced after the child realizes he is ill or that he no longer belongs to a family. This creates fear in the child compounded by an already existing physical illness.[14] The sooner a child is given correct information about his health status the easier it is for the child to trust those in charge of his care.

[13] Kon 2006.
[14] Hyworth 1972.

Regardless of what information these children receive, they are aware (or soon become aware) that they are ill. If a child is not given the ability to understand his illness and the purpose of research, research will appear to be medical care. When this assumption or misconception occurs, children usually do not question those in charge of their treatment,[15] especially when research shows that ill children believe they are receiving medical care. This is called the *therapeutic misconception.*

Research is simply research. It is not intended to be a substitute for health care or access to health care. It is beyond the scope of researchers to provide medical care or secure it for classes of people who lack access to health care. Even today, research trials are often confused with access to "state of the art" medical care.[16]

Researchers conducting Phase I trials have also been found to hold the view that their own clinical research was a way to provide a medical benefit to participants. A study done on researchers who conduct Phase I trials with children claimed many researchers believed that they were offering a direct benefit to the children when the only purpose of the study was to find the correct level of drug toxicity. There is no direct benefit, because the "studies are explicitly non-therapeutic in nature."[17]

Any reasonable adult could put himself in a hypothetical situation where he is told that he has contracted a disease without the hope of any approved treatment. That constitutes a burden not every person has or should have. Then, imagine being a child in this same hypothetical situation. On top of being young and vulnerable, imagine the

[15] Oberman et al 2003.
[16] Medicalnewstoday.com 2005.
[17] Oberman et al 2003.

situation ensuing with no family to turn to, with strangers shuffling you through the motions of an unapproved drug regimen without the guarantee of getting better.

The discussion about foster children isn't about a small handful of children who fall through the cracks, but about numerous lives that are affected by the very living conditions these children are forced into, set up for their own protection. HIV+ foster children differ from other healthy children of the same age. These children will have, and have had, experiences that differ from those of healthy children because these HIV+ children are ill and they reside separately from a biological or traditional family. I will argue, on the one hand, that these children have a greater ability to comprehend information about their illness, make autonomous choices due to the experiences, and on the other, that these children still deserve protection because they have been historically taken advantage of during medical research and are dependent on others for basic survival needs. We have a duty to protect these children by treating them with respect, by giving them information about their illness, and by allowing them a role in the decision-making process that surrounds participation in medical research.

As I will show, children who have a life-threatening illness have the ability to comprehend information about their illness and are better equipped to be involved in decisions regarding participation in medical research. New data in the area of childhood cognitive development conflicts with the traditional data that claimed children were only able to make decisions depending on the chronological age of the child. This new data shows that it is through experience that children learn to make decisions and not through attainment of a certain age. This ability to make decisions based on comprehension will depend on the individual child and what experiences he may have, rather than on a

chronological age he has reached. New data also conflicts with the traditional idea that terminally-ill children cannot and should not discuss their own illness or likelihood of death. This data also sheds light on the ability children have to understand death, which adds to the autonomy they possess and gives more weight to the ability of these dying children to be involved in decisions regarding enrollment and participation in medical research.

Chapter Two

Although every adult was first a child, not every child will survive to become an adult. It is important and ethical to treat children as persons if, for no other reason, than the fact that they are individuals who are capable of more than feeling pleasure and pain. Children are persons in their own right, independently of any conceptual dependence of childhood on adulthood. All children have unconditional worth. To give a child status because of what he may become in the future, is to deny their present existence. This becomes especially true when a child, through no fault of his own, is incapable of becoming an adult because he is dying.[18]

If we take into consideration the amount of knowledge a child has about the world and compare it to that of adults with the same socio-economic situation, children will have less knowledge than those adults. This implies nothing about a child's intellect, or more importantly, his moral worth. We find that adults, in comparison to other adults, will also have different levels of knowledge based on their experiences and socio-economic standing.[19] If the capacity for intellect or rational decision making is built upon our experiences, then experience may be the only thing that a child is lacking. However, the experiences of a child may be sufficient to allow him a part in decisions made on his behalf, especially decisions regarding disclosure of illness and participation in medical research.

[18] Benporath 2003.
[19] Benporath 2003.

Recent work in the area of children has contradicted the traditional position that it is age and not experience that gives children the ability to make decisions. Empirical data about children diagnosed with terminal illnesses, as well as studies of children residing in state sponsored foster care settings, shows that personal experience causes children to mature at different levels. Children in both categories encounter and experience things that are not typical of a healthy child who grows up in a traditional, biological family setting. When dealing with children who are both terminally ill and residing in foster care settings, it is both presumptuous and incorrect to treat them as though their capacities for comprehension are the same as those of other children of the same chronological age.

Past research on the ability of children to deal with death, as "an understanding of the biological state as a cease of biological function," purports to show that children do not fully comprehend this process of death until the age of nine. This research pertains to children who, for the most part, have never experienced a death other than that of a family pet. Research conducted as early as the seventies on how terminally ill children deal with death show that this past research is not conclusive as to stages of comprehension surrounding death as a cognitive ability of chronological age.[20]

Gareth B. Matthews claims that children understand a lot about death when they are dying from an illness. The understanding of death comes through experiencing the death of others, and the more children experience this, the more aware they become of death as a final step. Children who reside with other children who share the same life-threatening illness are more likely to experience the death of other children. Matthews

[20] Matthews 1994

holds that children usually deal with the idea of death better than adults who are obligated to care for them. Research that claims that children should be protected from knowing their terminal status to ease depression and anxiety is outdated. Children do better psychologically when they know their terminal status if they are given the ability discuss the death of other children and speak about the dying process. These children benefit emotionally from being involved in their health care decisions when they understand that they are dying, more so then when no information is given at all.[21]

Traditional research in this area claims that children are not capable of understanding death until they reach a certain chronological age, and that it is their cognitive development that enables them to understand fully the concept of death.[22] Gareth B. Matthews criticizes research inspired by the ideas of Piaget, based on chronological age.[23] This research does not take into consideration the individual experiences of each child. One example of this type of research is that of Susan Carey, who assumes the traditional position of how children understand death by claiming that the understanding of death occurs in three stages.

> In the first period, characteristic of children age 5 and under, the notion of death is assimilated to the notions of sleep and departure. The emotional import of death comes from the child's view of it as a sorrowful separation and/or as the ultimate act of aggression… In this period death is seen neither as final nor as inevitable. Just as one wakes from sleep or returns from a trip, so one can return from death. Although children associate death with closed eyes and immobility, as in sleep, they do not grasp the totality of the cessation of function…
>
> The second stage (early elementary years) in the child's understanding of death is transitional and is characterized differently in the different studies. All authors agree that children now understand the finality of death, and they understand the sense in which a dead person no longer

[21] Matthews 1994.
[22] Bluebond-Langner 1978.
[23] Matthews 1994.

> exists. However, children still see death as caused by an external agent… The child does not yet conceptualize death in terms of what happens within the body as a result of those external events…
>
> In the final stage death is seen as an inevitable biological process. Such a view of death first becomes evident around age 9 or 10… To [a] question about the causes of death, one sage 12-year-old answered, "When the heart stops, blood stops circulating, you stop breathing, and that's it… Well there's lots of ways it can get started, but that's what really happens."[24]

Gareth B. Matthews argues that acceptance of the traditional view of how children come to understand death causes adults to conform to

> "a completely paternalistic approach to children under nine years of age with respect both to (1) disclosure of diagnosis and prognosis and (2) consent to treatment. One is encouraged to think that, although the management of child patients ought to minimize patient distress, it need not, indeed, it *cannot* really, respect patient autonomy; the cognitive competence required for autonomy is simply missing in young children."[25]

This line of reasoning is problematic with children under the age of nine who are mature enough and will benefit from information about the nature of the illness, treatment options, and discussions surrounding the possibility of death. Mathews draws on the study done by Myra Bluebond-Langner and endorses her claim that children do not come to understand death when a certain age is reached; rather they do so owing to their own experience of knowing others who have died. The traditional view should be abandoned in an effort to provide foster children diagnosed with a life-threatening illness information and respect by allowing them a role in decisions regarding medical research.

The work of Myra Bluebond-Langner gives children a voice when dealing with the issue of how terminally ill children deal with death. These experiences that children

[24] Matthews 1994.
[25] Matthews 1994.

encounter allow them to become aware of death and their illness through five stages. None of these stages are dependent on chronological cognitive development.

> The children first learned that "it" (not all the children knew the name of the disease) was a serious illness. At this time, they also accumulated information about the names of drugs and their side effects. By the time the children reached stage 2, they knew which drugs were used when, how, and with what consequences. The third stage was marked by an understanding of the special procedures needed to administer the drugs and additional treatments that might be required as a result of the drugs' side effects. The children knew which symptoms indicated which procedures, and the relationship between a particular symptom and procedure. But they saw each procedure, each treatment, as a unique event. Not until they reached stage 4 were they able to put treatments, procedures, and symptoms into a larger perspective. By then, the children had an idea of the overall disease process –that the disease was a series of relapses and remissions, that one could get sick over and over again in the same way, and that the medicines did not always last as long as they were supposed to, if at all. But it was not until the fifth stage that the children learned the cycle ended in death. They realized that there were a finite number of drugs and that when these drugs were no longer effective, death became imminent.[26]

In a study that was conducted to see how children deal with a terminal illness psychologically, Dr. Roy V. Hyworth found that "Children develop their ideas about their illness from whatever source from which they can glean information." Depending on the amount of information children were given from either parents or doctors, the less they were told, the worse they thought their condition was. Other factors besides dying, such as "age, type of illness and treatment, separation from parents and home, painful, mutilating or body-changing experiences" all played a role in causing psychological distress in children, and the less they were given the chance to discuss their disease or have information about it, the more prone they became to psychological distress.[27]

[26] Bluebond-Langner 1978.
[27] Hyworth 1972.

If we draw from the work done by Gareth B. Matthews, Myra Bluebond-Langner, and Dr. Roy V. Hyworth we can conclude that it is better mentally and emotionally for the child to receive information about his illness and prospect of death. The children can suffer psychologically if information is not given and when they are not included in decision-making regarding the illness and treatment. Not allowing these children information and a role in this process is denying them respect as persons.

When discussing HIV, the benefits of disclosure outweigh the burdens. Children must know their status.

> "The fact is, they don't know, and it isn't a simple thing to tell them… According to Claude Mellins, co-founder and co-director of the Special needs Clinic at New York Presbyterian/Columbia hospital in New York, about 70 percent of her young patients with HIV do know their status by the time they're 10 or 11. Still, from the outside, the idea that any HIV – infected child – the other 30 percent—could reach adolescence without knowing he or she has the disease threatens to beggar belief."[28]

With HIV, there is more at stake if the illness is not disclosed, because the majority of these children today live well into adulthood.

> "There are two issues here, of course: 1) what's best for the long-term physical and mental health of … as he grows older and inevitably aware that an enormous secret has been kept from him; and 2) the prospect of a happy, charismatic, handsome young boy approaching the age of sexual activity who has HIV and doesn't know it."[29]

It is important that children are told that they are HIV+ as soon as possible. The longer these children live with this illness, but are not told what it is they have contracted, the harder it will become to disclose this to the child. This disclosure must occur long before the child reaches puberty or the age of sexual curiosity. The sooner the child is

[28] Dee 2005.
[29] Dee 2005.

abile to discuus his illness and the way the illness is contracted and spread, the better his chances for dealing effectively with issues such as sex, reproduction, and transmission. The amount of information a child is given, and the timeliness with which it is given, can affect the way the child views himself and how he deals with his illness.

When ensuring that these HIV+ foster children receive respect, the autonomy of the child is not the only factor that must be taken into consideration. These children have not only been diagnosed with a life-threatening illness; they also have been abandoned, orphaned, or removed from their families to reside in foster care settings. Protecting these HIV+ foster children should also be taken into consideration when dealing with the enrollment of these children in medical research. Foster children begin at a disadvantage and deserve both respect and protection in the form of benevolent paternalism.

The mere experience of state care decreases both the physical and mental health of these children because they "enter foster care in a poor state of health. In addition to abuse or neglect that commonly results in out-of-home placement, their poor health reflects exposure to poverty, poor prenatal care, prenatal infection, prenatal substance abuse, family and neighborhood violence, and parental mental illness."[30] The poor health these children are pre-disposed is then magnified with a life-threatening illness.

"Although the number of children in foster care initially declined in the early 1980's, increases in the incidence of substance abuse, single-parent families, homelessness, child poverty and child-abuse, as well as the emergence of human immunodeficiency virus (HIV) infection, resulted in even greater expansion of the foster

[30] Simms 2000.

care population." Around "78% of the children were considered to be at high-risk of HIV infection resulting from parental drug abuse, only 9% had been tested for the virus." Besides the mental status of these post-wards of the state, the socioeconomic status is also hindered. "One-third of youth formerly in foster care had incomes at or below the poverty level, one-third had no health insurance, and nearly a quarter had experienced homelessness after leaving foster care."[31]

Foster children as a class are disadvantaged physically, mentally, and emotionally. These children usually come into the foster care setting with poor health and mental issues. They usually do not have biological parents that can make medical decisions for them. When foster children suffer from an illness for which there is no treatment, the interest of the individual child should be a high priority.

The difficulty in dealing with this situation is that the state agency that is the guardian for these children is also responsible for their medical care.

> "Child welfare agencies are responsible for ensuring that children in their care and custody receive services to optimize their health and development. Although these agencies are responsible for the children receiving medical care, they are in no way authorized to consent for these children to be involved in research. Most agencies have continued to struggle with significant resource shortages in the face of increasing case loads, and children's health care has not been a priority for the child welfare system."[32]

Let's take the story of Jane.[33] Jane was a product of unfortunate events. Jane was five. She did not know who her father was, and as she was now at the age where the question came up, her mother had become so ill that she was hospitalized and Jane was

[31] Simms 2000.
[32] Simms 2000.
[33] Jane is a fictional character based on statistics of HIV+ foster children in the early 1990's in New York City.

unable to ask. Jane did not visit her mother and she wasn't sure if she was even allowed to visit.

Jane had not lived with her mother since she could remember. It was actually around the age of three that she was removed from her mother's home by the state welfare agency and brought to live with other children in her same situation. Jane's mother was dying from AIDS, the final stage of HIV. This was not the original reason that Jane was removed from her mother's home. Complaints from neighbors of child neglect and suspicions of the mother's drug use led the state welfare workers to remove Jane from the home long before her mother's health status was known.

Although Jane had lived in a tiny apartment with her mother, the Children's Home she lived in was the home she now knew. Jane did not understand what a normal life of a child her age was supposed to be. Jane knew that some children went to school or played with toys and she knew some children got sick and died. This was Jane's reality.

Jane also knew that it would not be long before her mother would die. When she was living with her mother, one of the few things she remembered was the death of her mother's boyfriend. He too, was very sick, and Jane thought he had the same disease her mother had. The boyfriend was not around long. What Jane remembered of him was that he became sick and shortly thereafter went to the hospital and died.

This was the first person that Jane knew that died. She thought that her mother would soon follow. Since the death of the boyfriend, Jane also knew of two other children at the Children's Home who had died. Although the adults there were reluctant

to discuss the child's illness, Jane assumed it was the same illness that she, her mother, and her mother's boyfriend had. Jane knew she was HIV+.

Jane was born to a drug-addicted mother who had contracted HIV long before she got pregnant with Jane but was unaware of her status. Jane became infected with the virus at birth. Jane was never tested until she came to live at the Children's Home. At this time, her mother's boyfriend had already died, Jane knew her mother was soon to follow, and she knew also that unless the doctors could help her, she too would die.

The experiences she was having were atypical of most five year old children. Jane had witnessed death numerous times. She was ill. She was now living with other children who were ill. She would watch the children suffer side effects. Sometimes she would see them recover; other times, she would never see them again.

At the age of five, abandoned, ill, Jane was seing the odds steadily stack up against her. The adults in her environment were hesitant to discuss with Jane what was occurring around her and to her. The normalcy of doctors and researchers, daily administration of medicine, throwing up and pain-- these were the main element's of Jane's five year old life. She began to put the picture together herself, absorbing any information she could. These experiences caused Jane to learn that death was immanent. Her understanding of death was not caused by some chronological brain development, but by the fact that these were her life experiences.

Jane had a lot of questions that no one was willing to answer. What she knew, she gathered from the adults talking around her when they did not think she was listening. Sometimes they sent mixed messages. Other things that Jane knew were discovered by

talking to the other children about their experiences with HIV and the treatments being used. Jane knew more than the adults realized, and the attitude of fear displayed by the adults, along with the lack of discussion, was beginning to take a toll on her mentally.

When Jane would visit the doctor she would always feel hopeful before she went, but then usually feel sick again after the appointment. One time she heard one of the adults at the Children's Home state that it was a shame that so many children had to die. Jane often thought that there was a chance the doctors could help her, but this man made her think that it was only a matter of time before death would come for her. She wanted to ask the doctors questions, but she was afraid she would upset them, and in no way did she want to upset the only people that could help her.

It was normal for Jane to feel both scared and guilty. Most children entering the foster care system will "feel a combination of fear of the unknown, guilt in having somehow brought about separation from their family, and a sense of being punished."[34] On top of being in a strange place, Jane was very ill. Jane was not at fault for the tragedies that occurred to her or her family, but she was a child. With nowhere else to go and no one else to care for her, Jane was again faced with another experience of life, living in state custody, something no child should have to deal with. Whether it was the only choice for Jane, or the best choice for Jane, being separated "from one's family, even an abusive one, is generally traumatic for children."[35] This event for Jane was

[34] Simms 2000.
[35] Simms 2000.

certainly unexpected. "Placement in foster care is rarely a planned transition for children."[36]

Jane should have been told she was HIV+ instead of being left to assume her HIV status. Jane also had a right to know how this virus would affect her immune system and her health. She also had a right to know that no treatment existed for HIV because it was such a new disease that doctors were still learning about. Jane should have also been told that she was participating in medical research and that her participation would enable doctors and researchers to find a safe effective treatment for HIV in children. Jane had the right to know the truth and to be involved in discussions about her illness and her participation in research.

The important issue is if HIV+ foster children participate in medical research, they are not unfairly burdened in the research studies. It is also important to the psychological health of the child to know and discuss the illness acquired and what it is they are participating in as a treatment option. These children, like Jane, deserve to know what is happening to them and when there is no treatment available. Jane, at the age of five, deserved to be told of her HIV infection. She also deserved a chance to discuss her illness, the fact that at this time no treatment existed, and that she was participating in medical research that was promising effective treatments for her and other children infected with HIV.

It is important to learn from the past mistakes of medical researchers so that we can learn how to improve in the future. If research is not conducted ethically, the harms

[36] Simms 2000.

that may transpire to the individual child or to public trust in the research community are too great a risk to take. HIV+ foster children in medical research should have been told of their illness and should have been given opportunity to discuss their illness with health care providers.

However, when it comes to the specifics of medical research, guidelines are in place and great pain should be taken to ensure all involved comprehend the delicacy of research but above all else, protect the interest of the child. The history of medical research has proven that children are a vulnerable class who deserve protection[37] and, therefore, safeguards have been put in place to ensure protection to these individuals. The history of the abuse that has occurred in research needs to be corrected so trust can be regained.

> "Edward Jenner used children (including his own infant son) in his work on small pox in the late 1700's. Joseph Lister used children in his work on wound infections. Louis Pasteur first tried his vaccine for rabies on a child who had been bitten by a rabid dog… In the early 20th century, children at the Hebrew Orphan asylum were fed diets known to induce scurvy and rickets so that these diseases might be better understood. Between 1958 and 1960, mentally challenged residents at Willowbrook State School were deliberately exposed to hepatitis so that researchers could gain a better understanding of the disease."[38]

Those in positions of power in the medical community have a duty to protect children. Children need to be protected from other persons in society that are quick to exploit them or use them for the purpose of attaining some ulterior goal. Children need to be protected because they are vulnerable,[39] yet protection by withholding information

[37] Barfield et al 2005.
[38] Barfield et al 2005.
[39] Benporath 2003.

is not and should not be justified, especially when this lack of information that the child does not receive harms him.[40]

Children are not vulnerable simply because they are children. Vulnerability entails an opportunity for those in power to take advantage of another individual.[41] Persons in society, or more specifically in the medical community, are able to take advantage of children if they abuse their positions of authority or disregard obligations that children are owed. As cynical as this may sound, the majority of this 'abuse of power' is done unintentionally, and for the most part, for the greater good.

In the above cases, children were not given a choice or a role in the decision-making process to participate in research, or told that what they were particpating in was research and not an approved medical treatment. These children were either enrolled by the state, or by their own parents, without any respect being offered to each individual child. The obligation to disclose an illness to a child should be placed on the research community, ensuring that the goals of individuals will be placed above the goals of research needs. This goal can be met through outside assurance from both IRB's and Independent Advocates for children. Medical research with children can occur where children are treated with respect. Medical research with children is essential to treating childhood illness and disease. Research must occur in order for children to benefit from advances in medical science.[42]

[40] Hyworth 1972.
[41] Sigal 2003.
[42] Barfield et al 2005.

Chapter Three

Foster children have no authority, no control, no economic means, and no decision-making power. What they do have despite this ideal concept of autonomy or individuality is a dependence on those in the power positions around them. They are dependent on others for shelter, clothing, education, values taught, security-- both physically and emotionally-- religion, hopes, medical care and decisions that the state will not allow them legally to make for themselves.

The balance between protecting individual children and allowing important medical research to go forward is delicate.[43] However, it is far more important to conduct ethical research, in which each child is offered respect and protection, than to conduct a higher quantity of medical research that may harm individual children but benefit the population of children as a whole. In cases where children are in foster care, coupled by the fact that the illness they have acquired is life-threatening, these trials must be conducted at a higher ethical standard.

HIV+ foster children are faced with many factors that will add to their vulnerability when participating in medical research. Factors will include but are not limited to such things as living in foster care, dealing with the daily hardships and deteriorating conditions of a life-threatening illness, the therapeutic misconception, psychological issues related to abandonment issues, poor health, guilt and shame. These children are autonomous yet still deserve protection.

[43] Whittle et al 2004.

The first safeguard that should always be followed when conducting medical research with HIV+ foster children is disclosure. Regardless of whether or not any treatment exists outside of research a child at any age has the right to know what his illness is and how this illness will affect him. Because children often acquire the illness at birth, a discussion regarding disclosure and treatment options should be in place as soon as the child can comprehend and use language.

The second safeguard that should be put in place is allowing the child to assent. "Assent is a means of involving minors in treatment decisions. It is an interactive process between a minor and a physician that involves developmentally appropriate disclosure about the illness, and solicitation of the minor's willingness and preferences regarding treatment."[44] This commonly accepted definition of assent as a minor's agreement to participate sets a lower standard of competence than informed consent because it does not require the depth of understanding or the demonstration of reasoning ability required for informed consent."[45]

Assent is just one of the many safeguards that is put in place to offer respect and protection to children and should be required of researchers when dealing with HIV+ foster children. Assent allows the child to discuss his illness, to be informed of whether or not treatment exists outside of medical research, and if research is the only option available, assent offers a mean to obtain information about what participating in medical research entails. The information the child receives will include such facts as these: that participation in the research is voluntary; that the research is not medical care; that the

[44] Committee on Bioethics, 1995.
[45] Kuther 2003.

trial has a specific goal; and that if the child agrees to participate in this medical research that at any time the child is free to withdraw. (The latter fact should be accompanied by the name and phone number of the person the child is to contact if he decides to withdraw.)

Assent offers the protection that children deserve by respecting them as individuals. The assent requirement falls under the scope of respect for persons because this principle "incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection."[46] Children are protected in research by requiring parents, guardians, or independent advocates to consent for them to participate. While the informed consent process allows parents, guardians, or independent advocates to make an informed choice in the best interest of the child, by requiring assent, it shows that each child is aware he is participating in research.

The legal guardian of foster children is either the state agency or the foster family caring for them. In dealing with assent issues for these children to be involved in medical research, the foster parents and state agencies have no authority. While some argue that this regulation 45 CFR 46.409 should be relaxed[47] to allow this, experts in the area of medical research claim that the "best interest of the child" is better sought through the use of independent advocates and Institutional Review Boards.

The responsibility of conducting ethical research by obtaining the assent of children is delegated to the IRB through 45 CFR 46.408 (a), which states: In addition to

[46] NBAC 1979.
[47] McNutt 1994.

the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in judgment of the IRB the children are capable of assenting, the IRB must take into account the ages, maturity, and psychological state of the children involved… the assent of the children is not necessary condition for proceeding with the research. If no treatment exists outside of research and an independent advocate for that child agrees to the child being enrolled in research approved by an IRB, then a child's desire to not participate may be overridden when this research is deemed to be in the best interest of that child. This is also holds true for very young children or infants who do not yet have the capacity to assent.

The necessity of assent of children in medical research can be traced back to the ethical principles outlined in the Belmont Report. The Belmont Report outlines its basic ethical principles as respect for persons, beneficence, and justice.[48] Alexander Kon states that the first of these ethical principles, respect for persons, is the basis for the majority of debate surrounding assent.[49] Other ethicists have argued, "The assent requirement is rooted in respect for the principle of autonomy."[50] Because children deserve both respect and protection, the assent requirement should be rooted in *respect for persons*. This view upholds the respect that is owed to all participants regardless of their age or mental capacity while still offering protection.

If we take the principle *respect for autonomy*, it is lacking to some degree when dealing with children. "To respect an autonomous agent is, at minimum, to acknowledge

[48] NBAC 1979.
[49] Kon 2006.
[50] O'Lonergan 2006.

that person's right to hold views, to make choices, and to take actions based on personal values and beliefs. Such respect involves respectful *action,* not merely a respectful *attitude.*"[51] According to this view, respect requires more than the mere *claim* that a child is respected during research. It requires the further step of requiring disclosure and assent to make that *claim* an *action.* The assent requirement provides the proof that the child has been involved in the decision-making process to participate in research. "Respect, on this account, involves acknowledging decision-making rights and enabling persons to act autonomously, whereas disrespect for autonomy involves attitudes and actions that ignore, insult, or demean others' rights of autonomy."[52]

According to the deontologist Immanuel Kant, respect for autonomy is owed even to persons who lack full autonomy. "Kant argued that respect for autonomy flows from the recognition that all persons have unconditional worth … To violate a person's autonomy is to treat that person merely as a means, that is, in accordance with others' goals."[53] According to this ethical theory, requiring and obtaining the assent of each child must occur or the goals of medical research outweigh the worth of each child. Each child deserves to be an end in himself, and as Kant stated, "every rational being, *exists* as an end in himself, *not merely as a means* for arbitrary use by this or that will: he must in all his actions, whether they are directed to himself or to other rational beings, always be viewed *at the same time as an end.*"[54] This concept of autonomy offers a basis; one that recognizes that *all persons have unconditional worth.* While this is sufficient to ensure

[51] Beauchamp et al 2001.
[52] Beauchamp et al 2001.
[53] Beauchamp et al 2001.
[54] Pojman 2002.

that disclosure occurs or that more mature children are treated with respect, it does not take into consideration the complexities of medical research with HIV+ foster children.

When dealing with children, autonomy would better be defined as *individuality* rather than the acknowledgement of *decision-making rights* or the enabling of a child *to act autonomously*. Utilitarian, John Stuart Mill placed the emphases of the concept of autonomy on *individuality*. "He argued that society should permit individuals to develop according to their convictions, as long as they do not interfere with a like expression of freedom by others; but he also insisted that we sometimes are obligated to seek to persuade others when they have false or ill-considered views."[55] Mill also "considered temporary beneficent interventions in a person's actions to be justified on some occasions."[56]

I contend that the requirement of disclosure and child assent is grounded in the ethical principle of *respect for persons*, which encompasses both autonomy and paternalism. The Belmont Report states "The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy."[57] Because foster children are vulnerable and lack any real power, it is not enough to allow them autonomous choices. In addition they deserve respect, which entails protection as a form of justified paternalism.

[55] Beauchamp et al 2001.
[56] Beauchamp et al 2001.
[57] NBAC 1979.

"Intervention in the life of a substantially non-autonomous dependent became and remains the most widely accepted model of justified paternalism."[58] In the case of children, especially those who are not under the custody of a biological parent, IRB's and independent advocates should be allowed to exercise this paternalism. Specific federal guidelines are set up to ensure this advocate for the child is independent of the agency that is set up to care for the child.[59] Whether ethicists claim that assent is grounded in the principle of respect for persons or the principle of respect for autonomy, the basis of the argument encompasses the need to respect these children as autonomous while acknowledging the fact that they do not have the same power or authority as adults and are in need of protection from adults who can ensure that whatever it is that occurs is done in their best interest.

The two aspects of this principle do not need to be in conflict. The principles of autonomy and paternalism coexist under the principle *respect for persons* because when a child is told of his illness or required to assent to participation in research, he is not in exchange giving up his right to be protected. As noted in the Belmont Report, "respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research." This allows assent to play a different role with each child based on that child's individual need and ability to comprehend information about both his illness and medical research.

The protection of children is not diminished when certain aspects of the research study are disclosed to them. When a child is required to assent to be involved in medical

[58] Beauchamp et al 2001.
[59] 45 CFR 46.409

research, none of the other protective safeguards are sacrificed. Just because assent is required, it does not diminish the protection of these children.

Children at any chronological age should be protected despite their ability to assent, or the presence of the requirement for assent. If the child does not have the ability to assent in situations where language is not yet developed, these children should not be denied access to research trials. This is extremely important with HIV+ foster children because "More than 95% of children under thirteen years old who are diagnosed with HIV are infected during pregnancy or birth from exposure to an infected mother."[60] These children should not have to wait until they are at an age of comprehension to be enrolled. If researchers wait until an age of maturity to place these children in research, it is often too late to slow the growth of the retrovirus. Without the enrollment of these young children in research trials, no treatment can be made available to other children of the same age.

One exception to the assent requirement is that "a child's objection may be overridden when research holds out the prospect of direct benefit to participants that is important to the child's health or well-being and is available only in the context of research."[61] Therefore, exceptions to the assent requirement can be made, but when at all feasible, assent should be obtained. Because the federal regulations are not legally binding, but serve to offer guidance, IRBs are supposed to uphold the protection that children are owed when they are involved in research.

[60] Cox.et al.
[61] 45 CFR 46.

Because so much of the assent process depends on the research and the comprehension level of the child, IRBs carry the majority of the responsibility in ensuring that the balance of respect and protection are offered. A survey was conducted to determine if IRBs were carrying out this task correctly.[62] It was concluded that "there is a wide variation in which children are considered able to give assent, how ability to give assent is determined, whether children who are unable to give assent are enrolled in non-beneficial research when their participation is unnecessary." The variation serves as a good balance depending on different aspects of the study. It was found that "(99%) of IRBs require children to be informed that they can refuse to participate, of the purpose of the study (97%), of a description of common risks (97%), and whether they will benefit (94%). Fewer IRBs (73%) require investigators to inform children of serious but rare risks."[63]

This survey of how IRBs implement the assent process shows that the assent requirement does and can serve its purpose in medical research with children. "At a minimum, most agree that an assent discussion should contain at least an overview of the basic study procedures, a disclosure that participation is voluntary, and an explanation that what the child is being asked to agree to is research rather than medical care per se."[64] This ensures that the child is given a level of involvement, while still being protected.

Assent in younger children should serve a different purpose than assent in older children. Younger children should not be told all aspects of the research study, but if a

[62] Whittle et al 2005.
[63] Whittle et al 2005.
[64] Kon 2006.

child is at an age where he can comprehend all aspects involved in an informed consent process, then all of this information should be divulged.[65] The important aspect of the assent requirement is not so much the age it is required at, but the degree of information the child receives, which should be tailored to the capacity of the child. Certain aspects of the assent discussion may be left out without the research becoming unethical. These omitted items should be relevant to the needs of each individual child.

Assent creates a way for medical research to proceed ethically by "giving them [children] a voice in whether they participate in research."[66] By giving them a voice, children are not only given the ability to understand what they are participating in, but they are given the ability to discuss the illness and whether or not treatment is available outside of research. Even if they are unable to understand all aspects of a research study, the assent process allows them to differentiate between the voluntary nature of research and medical treatment.

While assent procedures are mainly up to IRBs to implement, I think it is important that flexibility exists when dealing with this issue. Not all medical research will carry the same benefits or risks, and not all children have the same level of understanding. The assent requirement should be maintained for all children involved in research when treatment exists that is both safe and effective, even if it requires nothing more than informing the youngest of children that that their participation is voluntary and a minimal discussion has taken place. However, in situations where foster children have acquired a life-threatening illness and no approved treatment exists, IRB's should be

[65] Kon 2006.
[66] Whittle et al 2004.

allowed to waive the assent requirement when it is in the best interest of the child. The IRB should require that each child is told of his illness and that what he is participating in is medical research and not medical care because no treatment at this time exists.

If the child is too young to understand, the discussion should take place as he reaches this level of understanding.

> "Children born with the virus also aren't born with the knowledge that they carry it; this was a nonissue when few survived infancy, but as the prognosis improved, the whole issue of disclosure – of what they know about their own disease, and who tells them, and when, and how… Over the last decade, the revolution in medical treatment of HIV has created a generation of young people whose unexpected maturation is both a miracle and an extraordinary challenge."[67]

In the early 90's, children born with HIV had a life expectancy of "two or three years… By 1999, the life span for children infected in the womb ranged from 8.6 to 13 years; today that life span – provided the children stay on their drug regimens – is open-ended, and their illness has turned strikingly from terminal to chronic."[68]

> Ben Banks, a 26-year-old who lives in Virginia, had a rare form of cancer in infancy; on the day of the physical exam that was supposed to mark his 10-year freedom from that cancer, when he was 12, it was discovered that he had contracted HIV from a blood transfusion. He came home from school, walked up the stairs and found his mother sitting on the bed sobbing, having just hung up the phone. "That was the doctor," she said. "You're HIV positive."
> …But Banks, having already survived cancer, was a remarkably resourceful teenager. He told his best friend, and a few other friends, and then a group of his classmates at James Madison University, and now he serves as a spokesman for the Elizabeth Glaser Pediatric AIDS Foundation. In 2003, he married. As for the turning point in his own understanding of his disease – from death sentence to manageable illness – It may have come when he was 17 and applied to the Make-a-Wish Foundation, which grants the wishes of extremely ill children. His application was disqualified. Stung, he called up his doctor. "Ben," the

[67] Dee 2005.
[68] Dee 2005.

> doctor said, "why don't you give that wish to a child who really needs it. You're not going anywhere."[69]

Treatment for HIV in children is available today because of the extensive medical research and many clinical trials that occurred with HIV+ children. Treatment options and drug regimens must be tested in children to be approved for use in children just as those drug regimens approved for adults must be tested in adults. Because of the vast amount of research that occurs when a new disease infects humans, the medical community is able to offer hope to those infected and to those individuals who become infected. This is why HIV, which was a death sentence 20 years ago, has been transformed from a terminal to a chronic illness. Infants, children, and adults can live with and manage HIV infection today. The medical community, the researchers, the IRB's, the doctors, the ethicists, and those who participate in all stages of clinical trials are so important to each individual in society.

When an individual is infected with HIV, he should not experience this illness alone or with some preconceived notion of secrecy which will lead only to shame and guilt. HIV+ children should be educated about their illness, treatment options, life style choices, and how to educate others about their illness. These children should proceed into adulthood with the same dreams and hopes that any child has.

Nothing gets accomplished if a person becomes cynical in applying ethics to practical situations. It is important not to take the view that a proper age requirement is not important or that disagreements surrounding disclosure or assent will never be decided. Debates are healthy in ethics especially if they are aimed at serving a common

[69] Dee 2005.

purpose. Both sides of the debate on disclosure and assent in children's research are aimed at the protection of the child and 'protection of the child' becomes the common goal. Therefore, regulations, recommendations, and IRBs must allow and ensure that medical research continues ethically by requiring that foster children who are diagnosed with a life-threatening illness are told of their illness and allowed to have a role in the assent process when participating in medical research under the consent of an independent advocate.

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Curriculum Vitae

Diana Dimitra Popov

EDUCATION	Indiana University Master of Arts in Philosophy Bioethics Concentration July 2008	
	Indiana University Bachelor of Arts with High Distinction Major in Philosophy	
EXPERIENCE	Indiana University -Purdue University, Indianapolis Department of Philosophy	
	Instructor - P120 Ethics	2007
	Instructor - P110 Intro to Philosophy	2007
COLLOQUIUM	MA Student and Adjunct Instructor, Department of Philosophy, SLA - Diana Popov "Foster Children in Medical Research: Giving Kids a Choice"	
AWARDS	Indiana University -Purdue University, Indianapolis Department of Philosophy	
	Recipient of Riteris Memorial Scholarship	2000 - 2001
	Indiana University Dean's List	1996 - 2002
SEMINARS	American Association of Philosophy Teachers	
	16th Biennial International Workshop/Conference	2006
	Fairbanks Ethics Lecture Series The Charles Warren Fairbanks Center for Medical Ethics	2006
	Seminars in Medical Humanities and Bioethics The Medical Humanities Program, IUPUI in Conjunction With The Indiana University Center for Bioethics	2006
CLINICALS	Clarian Health Partners - Indianapolis, IN Clinical Ethics Practicum	2006
ORGANIZATIONS	American Association of Philosophy Teachers Active Member	2006